UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE BRISTOL-MYERS SQUIBB CO. SECURITIES LITIGATION	07 Civ. 5867 (PAC) **FILED ELECTRONICALLY**

MEMORANDUM OF LAW OF BRISTOL-MYERS SQUIBB COMPANY IN SUPPORT OF MOTION TO DISMISS

Lorin L. Reisner
Michael R. Potenza
Jacob W. Stahl
DEBEVOISE & PLIMPTON LLP
919 Third Avenue
New York, New York 10022
(212) 909-6000

Attorneys for Defendant Bristol-Myers Squibb Company

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Defendant Bristol-Myers Squibb Company ("BMS" or the "Company") submits this memorandum of law and the accompanying declaration of Lorin L. Reisner ("Reisner Decl.") in support of its motion to dismiss the purported Amended Class Action Complaint ("Am. Complaint").

PRELIMINARY STATEMENT

This action challenges BMS public disclosures concerning the Company's attempt to settle patent litigation with Apotex Inc. ("Apotex") involving the prescription pharmaceutical product Plavix. The Amended Complaint is meritless and should be dismissed for three independent reasons:

First, the Company's public filings provided accurate and complete disclosure as a matter of law. BMS disclosed that there was a "significant risk" that required regulatory approval of the Plavix settlement would not be obtained; that Apotex could launch a generic Plavix product in the absence of a settlement; and that serious adverse financial consequences would result from generic competition. *See*, *e.g.*, Reisner Decl. Ex. E (Form 8-K filed March 21, 2006). There was no legal duty to make additional disclosure concerning the proposed settlement. In particular, public disclosure of the information that plaintiffs claim was improperly omitted was not required under the applicable legal standard because the alleged omissions did not make the statements that were made materially misleading. *See infra* at 9-16.

Plaintiffs' principal allegation – that not reporting more detailed information about damages and procedural limitations that would take effect if the settlement were not approved, "rendered" BMS statements that it would "vigorously pursue" enforcement of its patent rights and that an Apotex generic launch would be "at risk" false, Am.

Complaint ¶¶ 3, 37, 60, 64, 66, 68, 72, 75, 78 – fails because the challenged statements were true and accurate. The Amended Complaint itself and other information of which the Court properly may take judicial notice demonstrate that BMS did, in fact, "vigorously pursue" enforcement of its patent rights and that Apotex's launch was "at risk."

BMS vigorously pursued its patent rights against Apotex: it sought and obtained a preliminary injunction within 23 days of the Apotex launch, *Sanofi-Synthelabo v. Apotex Inc.*, 488 F. Supp. 2d 317, 321 (S.D.N.Y. 2006); it vigorously presented its case at trial and prevailed, *Sanofi-Synthelabo v. Apotex Inc.*, 492 F. Supp. 2d 353, 397-98 (S.D.N.Y. 2007); it continues vigorously to pursue additional relief from Apotex. *Id.*; Reisner Decl. Ex. W (docket sheet). The Apotex launch obviously was at risk: the launch was at risk of being enjoined and was preliminarily enjoined prior to the 180-day exclusivity period that otherwise would have applied under the Hatch-Waxman Act, *Sanofi-Synthelabo*, 488 F. Supp. 2d at 344; the launch was at risk of being permanently enjoined and was permanently enjoined, *Sanofi-Synthelabo*, 492 F. Supp. 2d at 397-98; the launch also was at risk of exposing Apotex to the payment of substantial damages and Apotex was and remains at risk of being ordered to pay substantial damages. *Id.* at 397. Plaintiffs' allegations are thus meritless based on the absence of any legal duty to make further disclosure and the accuracy of the disclosure made. *See infra* at 11-16.

Second, plaintiffs cannot establish loss causation, a required element of their securities law claims, as a matter of law. The stock-price declines identified in the Amended Complaint plainly were linked to risks that were clearly disclosed: regulatory non-approval of the proposed settlement and an Apotex generic launch. Where, as here,

the economic harm alleged resulted from risks that were accurately disclosed, there can be no loss causation as a matter of law. Accordingly, the claims in the Amended Complaint also fail on this basis. *See infra* at 17-20.

Third, plaintiffs fail to and cannot satisfy the heightened requirements for pleading scienter applicable under *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 127 S.Ct. 2499, 2509 (2007). In particular, there is no basis for a "strong inference" of scienter given the absence of any obvious duty to make additional disclosure and the facts pleaded in the Amended Complaint. *See infra* at 20-24.

The Amended Complaint should therefore be dismissed.

STATEMENT OF FACTS[1]

BMS, through its divisions and subsidiaries, is engaged in the discovery, development, licensing, manufacturing, marketing, distribution and sale of pharmaceutical and other health care related products. Am. Complaint ¶ 15. Together with its co-venturer, Sanofi-Aventis S.A. ("Sanofi"), BMS markets the prescription drug Plavix in the United States. *Id.* ¶ 30. Plavix is a widely-prescribed platelet aggregation inhibitor used to protect against heart attacks and strokes. *Id.* In November 2001, Apotex, a Canadian company, filed an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA"), seeking approval to manufacture and sell a generic form of Plavix (clopidogrel bisulfate) prior to the November 11, 2011 expiration of the primary patent covering Plavix. Am. Complaint ¶¶ 30-31. BMS and

[1] The well-pleaded allegations in the Amended Complaint are taken as true solely for the purposes of this motion. *Sec. Investor Protection Corp. v. BDO Seidman LLP*, 222 F.3d 63, 68 (2d Cir. 2000).

Sanofi filed a lawsuit against Apotex in March 2002 claiming infringement of the Plavix patent. Am. Complaint ¶ 32. Apotex thereafter filed a counterclaim alleging patent invalidity and unenforceability. The Plavix lawsuit triggered a 30-month automatic statutory stay of FDA approval of Apotex's ANDA. *Id.* That stay expired in May 2005, and the FDA approved Apotex's ANDA on January 20, 2006. *Id*.

In early 2006, BMS and Apotex began discussions regarding possible settlement of the Plavix litigation. On March 17, 2006, BMS and Apotex entered into a proposed settlement agreement to resolve the litigation. Am. Complaint ¶ 33. In accordance with the terms of a prior consent decree, the settlement agreement was subject to regulatory review and approval by the U.S. Federal Trade Commission (the "FTC") and state attorneys general. *Id.* ¶ 34.

BMS publicly announced that the proposed settlement had been entered in a press release and Form 8-K issued on March 21, 2006. Am. Complaint ¶ 33-34; Reisner Decl. Ex. E (Form 8-K issued March 21, 2006).[2] The announcement described key terms of the proposed settlement, including that BMS would grant Apotex a license to sell its generic product effective September 17, 2011, that Apotex would not sell its generic product prior to that date, and that the agreement involved payments to Apotex that would be made equally by BMS and Sanofi. Am. Complaint ¶ 33; Reisner Decl. Ex. E.

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[2] "In deciding a motion to dismiss, the court may consider . . . public disclosure documents that are required by law to be, and have been, filed with the SEC." *Leykin v. AT&T Corp.*, 423 F. Supp. 2d 229, 237 (S.D.N.Y. 2006) (citing *Kramer v. Time Warner, Inc.*, 937 F.2d 767, 773-74 (2d Cir. 1991)). The court also may consider documents incorporated by reference in the Amended Complaint. *Roth v. Jennings*, 489 F.3d 499, 509 (2d Cir. 2007).

The BMS announcement cautioned that the proposed settlement was subject to regulatory review and approval by the FTC and state attorneys general and that there was a "significant risk" that this clearance would not be obtained. Reisner Decl. Ex. E. BMS further cautioned that if the agreement were not approved, the Plavix patent litigation would be reinstated, Apotex could launch its generic product at risk, and that generic entry would have serious adverse financial consequences for the Company. *Id.* The disclosure stated, in relevant part:

> The proposed settlement is subject to certain conditions, including antitrust review and clearance by the Federal Trade Commission and state attorneys general. **There is a significant risk that required antitrust clearance will not be obtained.** In such event, the proposed settlement would be terminated, and the litigation would be reinstated in the same Court . . . . It is not possible at this time reasonably to assess the outcome of this lawsuit or the timing of the potential generic competition for Plavix®. Apotex announced in January 2006 that it had received final approval of its aNDA for clopidogrel bisulfate from the FDA. **As a result, if the litigation were reinstated, Apotex could launch a generic clopidogrel product at risk**. . . . [L]oss of market exclusivity of Plavix and the subsequent development of **generic competition would be material to . . . Bristol-Myers Squibb's sales of Plavix® and results of operations and cash flows, and could be material to . . . Bristol-Myers Squibb's financial condition and liquidity.**

Id. (emphasis added).[3]

Following objections by the regulators to certain provisions of the proposed agreement, BMS and Sanofi attempted to negotiate a revised agreement. Am. Complaint ¶¶ 38-39. On May 12 and May 24, 2006, Dr. Andrew Bodnar, then Senior Vice President

[3] BMS made similar disclosure in an April 27, 2006 press release and Form 8-K announcing first quarter financial results, and in its Form 10-Q filed on May 8, 2006. Am. Complaint ¶¶ 67, 73; Reisner Decl. Exs. F, G. BMS had provided disclosure concerning the Plavix litigation in every quarterly and annual report filed following commencement of the litigation in May 2002. *See, e.g.*, Reisner Decl. Exs. A, B, C & D.

of Strategy and Medical & External Affairs for BMS, met with representatives of Apotex for negotiations in Toronto. *Id.* ¶ 39.

The parties entered into a revised agreement on May 26, 2006 that was subsequently submitted for regulatory review and approval. *Id.* The Amended Complaint alleges that the Company did not inform the FTC of certain "oral side agreements" made during the May 12 and May 24 meetings. *Id.* at ¶¶ 42-46.

On June 25, 2006, BMS issued an update on the status of the proposed settlement and regulatory review. Am. Complaint ¶¶ 40, 79; Reisner Decl. Ex. H (BMS release dated June 25, 2006). This update reported that the parties had entered into a revised settlement agreement in response to concerns raised by the regulators and that the revised agreement remained subject to regulatory clearance. Reisner Decl. Ex. H. BMS again cautioned that "there remains a significant risk that antitrust clearance will not be obtained." *Id.*

On July 27, 2006, BMS announced that it had learned that the Antitrust Division of the U.S. Department of Justice (the "Antitrust Division") was conducting an investigation regarding the Plavix settlement. Am. Complaint ¶ 52; Reisner Decl. Ex. I (Form 8-K filed July 27, 2006). The next day, July 28, BMS reported that the proposed settlement agreement had failed to receive the required regulatory clearance. Am. Complaint ¶ 87; Reisner Decl. Ex. J (BMS release dated July 28, 2007). Following these announcements, the price of BMS stock fell from $25.99 on July 26, 2006 to $23.97 on

July 31, 2006, the first trading day after the July 28 announcement. Am. Complaint ¶ 52; Reisner Decl. Ex. R.[4]

On August 8, 2006, Apotex launched its generic product. Am. Complaint ¶ 99; *Sanofi-Synthelabo*, 488 F. Supp. 2d at 325; Reisner Decl. Ex. S (Apotex release dated August 8, 2006). The share price of BMS stock declined from $22.77 to $21.21 on the day of the Apotex launch. Reisner Decl. Ex. R; Am. Complaint ¶ 96.[5]

On August 31, 2006, BMS obtained a preliminary injunction prohibiting Apotex from selling its generic product. *Sanofi-Synthelabo*, 488 F. Supp. 2d at 321; Reisner Decl. Ex. L (BMS release dated August 31, 2007). The following trading day, the price per share of BMS stock increased from $21.75 to $22.95. Reisner Decl. Ex. R. On December 8, 2006, the Court of Appeals for the Federal Circuit affirmed the District Court's decision. *See Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1470 (Fed. Cir. 2006); Reisner Decl. Ex M (BMS release dated December 8, 2006). That same day, the price per share of BMS stock increased from $25.25 to $25.35, Reisner Decl. Ex. R. Following a bench trial, on June 19, 2007, Apotex was permanently enjoined from manufacturing or selling its infringing product based on findings that the Plavix patent was valid and had been infringed by Apotex. *Sanofi-Synthelabo*, 492 F. Supp. 2d at 356;

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[4] The Court may take judicial notice of stock prices of publicly traded companies on a motion to dismiss. *See, e.g., Miller v. Lazard, Ltd.*, 473 F. Supp. 2d 571, 578 (S.D.N.Y. 2007) (citing *Ganino v. Citizens Utilities Co.*, 228 F.3d 154, 167 n.8 (2d Cir. 2000)).

[5] Also on August 8, 2006, BMS filed its Form 10-Q for the period ended June 30, 2006. Reisner Decl. Ex. K; Am. Complaint ¶ 95. BMS attached copies of the initial and revised Plavix settlement agreements as exhibits to this filing and provided a description of their terms.

Reisner Decl. Ex. Q (BMS release dated June 19, 2007). On that day, the price per share of BMS stock increased from $30.31 to $31.58. Reisner Decl. Ex. R.

On May 10, 2007, BMS announced that it had reached an agreement in principle with the Antitrust Division to resolve its investigation. Am. Complaint ¶ 107; Reisner Decl. Ex. O (BMS release dated May 10, 2007). Under the agreement, the Company agreed to plead guilty to two counts of violating 18 U.S.C. § 1001 and to pay a fine of $1 million. Am. Complaint ¶ 107; Reisner Decl. Ex. O. The charges related to "representations made by a former Bristol-Myers Squibb senior executive during the renegotiation of the proposed [Plavix] settlement agreement in May 2006 that were not disclosed to the U.S. Federal Trade Commission." Am. Complaint ¶ 56; Reisner Decl. Ex. O. BMS entered its guilty plea on June 11, 2007. Am. Complaint ¶ 108; Reisner Decl. Ex. P (BMS release dated June 11, 2007).

This action initially was filed on June 20, 2007 by plaintiff Minneapolis Firefighters' Relief Association. On September 20, 2007, Ontario Teachers' Pension Plan Board was appointed lead plaintiff. The Amended Complaint, which was filed on October 15, 2007, purports to be a class action on behalf of all persons who purchased BMS common stock from close of the market on March 21, 2006 through August 8, 2006. Am. Complaint ¶ 20. It contains four claims: (1) alleged violations of Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 against BMS and defendant Peter Dolan, Am. Complaint ¶¶ 129-44; (2) alleged violations of Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 against defendant Andrew Bodnar, *id.* ¶¶ 145-55; and (3-4) alleged violations of Section 20(a) of the Securities and

Exchange Act of 1934 against each of Dolan and Bodnar purportedly acting as "controlling persons" of BMS, *id.* ¶¶ 156-75.

ARGUMENT

I. THE COMPANY'S PUBLIC FILINGS PROVIDED ACCURATE AND APPROPRIATE DISCLOSURE AS A MATTER OF LAW.

A. No Additional Disclosure Was Required Concerning the Terms of the Proposed Plavix Settlement.

The Company's public filings provided accurate and complete disclosure as a matter of law. BMS disclosed the "significant risk" that regulatory approval of the Plavix settlement would not be obtained; that Apotex could launch a generic Plavix product in the absence of a settlement; and the serious adverse financial consequences that would result from generic competition. *See* Reisner Decl. Ex. E; *supra* at 5. The allegation in the Amended Complaint that more detailed disclosure concerning the terms of the proposed settlement agreement was required, Am. Complaint ¶¶ 60, 62, 64, 66, 68, 72, 75, 78, 80, is incorrect as a matter of law.

Where, as here, "an allegation of fraud is based upon nondisclosure, there can be no fraud absent a duty to speak." *Chiarella v. United States*, 445 U.S. 222, 235 (1980). A corporation is required to make disclosure under Section 10(b) of the Exchange Act only in three circumstances, none of which apply here: (1) when it is engaged in "insider trading"; (2) when a "statute or regulation require[es] disclosure"; or (3) where "silence would make other statements misleading or false." *Glazer v. Formica Corp.*, 964 F.2d 149, 157 (2d Cir. 1992) (affirming dismissal of securities fraud claims); *In re Canandaigua Sec. Lit.*, 944 F. Supp. 1202, 1208 (S.D.N.Y. 1996) (dismissing claims); *Oran v. Stafford*, 226 F.3d 275, 285-86 (3d Cir. 2000) (Alito, J.) (duty to disclose arises

"when there is insider trading, a statute requiring disclosure, or an inaccurate, incomplete or misleading prior disclosure") (citing *Glazer*, 964 F.2d at 157). There is no separate "affirmative duty of disclosure." *Glazer*, 964 F.2d at 157 (citing *Backman v. Polaroid Corp.*, 910 F.2d 10, 12 (1st Cir. 1990)).

The Amended Complaint does not allege any insider trading or that any independent statute or regulation required additional disclosure. Indeed, a registrant is required only to "[d]escribe briefly" in its annual and quarterly reports any material pending litigation, including "the name of the court," the "principal parties," a description of the "factual basis" for the claims and the "relief sought." 17 C.F.R. § 229.103 ("Item 103" of Regulation S-K); *see Wielgos v. Commonwealth Edison Co.*, 892 F.2d 509, 518 (7th Cir. 1989) ("[n]othing [in Item 103 requires disclosure] about the status of litigation within the tribunal, or how the tribunal is organized, or the probability that the tribunal will deliver a particular decision"); *In re Boston Scientific Corp. Sec. Litig.*, 490 F. Supp. 2d 142, 154 (D. Mass. 2007) (no duty under Item 103 to disclose litigation strategy or settlement prospects). The BMS annual and quarterly disclosures easily met these standards.

The additional information that the Amended Complaint alleges should have been included in BMS public filings also was not required because the absence of this information did not make other BMS statements false or misleading. *See Glazer*, 946 F.2d at 157 (to be actionable, alleged omission must "make other statements misleading or false"); *In re Progress Energy, Inc. Sec. Litig*., 371 F. Supp. 2d 548, 552 (S.D.N.Y. 2005) ("in order to state a claim . . . the omission of the information must have made statements that were made materially misleading") (citations omitted).

Plaintiffs' principal allegation is that BMS should have publicly reported information about damages concessions and procedural limitations that would take effect under the settlement if it were not approved. Am. Complaint ¶¶ 60, 62, 64, 66, 68, 69, 72, 75, 78, 80. For example, plaintiffs allege that BMS should have disclosed that under the initial Plavix settlement agreement, BMS agreed, in the event regulatory approval was not granted, to a damages limit of 70% of Apotex net sales; not to seek treble damages; not to request a trial earlier than 2½ months after the request; and not to seek a TRO or preliminary injunction until five business days after giving business notice or until after Apotex launched its generic product. Am. Complaint ¶ 60. Similarly, plaintiffs allege that BMS should have disclosed that under the revised settlement agreement, BMS agreed, in the event regulatory approval was not granted, to a damages limit of 50% of Apotex net sales; not to seek treble damages; not to request a trial date earlier than 2½ months after the request; and not to seek a TRO in any event or to seek a preliminary injunction until five business days after giving Apotex notice following its launch of a generic product. *Id.* ¶ 80.

The Amended Complaint alleges that the absence of this information rendered false and misleading the statements that BMS would "vigorously pursue" enforcement of its patent rights and that an Apotex launch would be "at risk." *Id.* ¶¶ 60, 62, 64, 66, 68, 69, 72, 75,78, 80, 86, 88. This argument fails because the challenged statements were and remain true and accurate. BMS did, in fact, "vigorously pursue" enforcement of its patent rights. BMS sought and obtained a preliminary injunction within 23 days of the Apotex launch. *Sanofi-Synthelabo.*, 488 F. Supp. 2d at 321. BMS vigorously presented its case at trial and prevailed. *Sanofi-Synthelabo*, 492 F. Supp. 2d at 397-98. BMS

continues vigorously to pursue additional relief from Apotex, *id.* at 397; Reisner Decl. Ex. W (docket sheet from pending action).[6] The statement that BMS would vigorously enforce its patent rights is thus demonstrably true and therefore not actionable as a matter of law. *See Int'l Bus. Machs. Corp. Sec. Litig.*, 163 F.3d 102, 107 (2d Cir. 1998) (statements that are neither false nor inaccurate not actionable); *In re Nokia Oyj (Nokia Corp.) Sec. Litig.*, 423 F. Supp. 2d 364, 393 (S.D.N.Y. 2006) ("Although obvious, it also bears noting that it is well settled that a complaint alleging violations of the securities laws may not rely upon statements that are true") (quotation omitted).[7]

The Apotex launch obviously was at risk. The launch was at risk of being enjoined and was preliminarily enjoined prior to the 180-day exclusivity period that otherwise would have applied under the Hatch-Waxman Act. *Sanofi-Synthelabo*, 488 F. Supp. 2d at 344. The launch was at risk of being permanently enjoined and was permanently enjoined. *Sanofi-Synthelabo*, 492 F. Supp. 2d at 356. The launch also was

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[6] The Court properly may take judicial notice of court decisions and docket sheet information. *Pani v. Empire Blue Cross Blue Shield*, 152 F.3d 67, 75 (2d Cir. 1988) ("district court may rely on matters of public record in deciding a motion to dismiss under Rule 12(b)(6), including case law and statutes"); *Mangiafico v. Blumenthal*, 471 F.3d 391, 398 (2d Cir. 2006) ("docket sheets are public records of which the court could take judicial notice").

[7] The statement that BMS would "vigorously pursue" its patent rights also is properly understood as a form of inactionable puffery that would not be relied upon by a reasonable investor. *See Lasker v. New York State Elec. & Gas Corp.*, 85 F.3d 55, 58 (2d Cir. 1996) (statement that "business strategies [would] lead to continued prosperity," consist of "precisely the type of 'puffery' that this and other circuits have consistently held to be inactionable"); *In re SeaChange Int'l, Inc.*, No. 02-12116 (DPW), 2004 U.S. Dist. LEXIS 1687, at *23-*28 (D. Mass. Feb. 6, 2004) (rejecting claim that statement that company "plan[ned] to oppose the allegations against us and assert our claims against the other parties vigorously" was misleading, particularly "given the well understood vagaries of litigation").

at risk of exposing Apotex to the payment of substantial damages and Apotex remains at risk of being ordered to pay substantial damages. *See id.* at 397 ("Damages will be set at an amount to be determined at future proceedings"). As Judge Stein observed in enjoining the launch: Apotex "conduct[ed] . . . ***an at-risk launch*** in advance of a determination on the merits of its defenses in this litigation that the '265 patent is invalid and unenforceable." *Sanofi-Synthelabo*, 488 F. Supp. 2d at 344 (emphasis added).[8]

Accordingly, the statements that plaintiffs allege were misleading are not actionable as a matter of law because they were and remained true. *In re Nokia Oyj Sec. Lit.*, 423 F. Supp. 2d at 393. In the end, the Amended Complaint "merely sound[s] the familiar refrain that any comment by a corporation imposes an affirmative duty to disclose all marginally-related material information. There is no such obligation or duty." *In re Canadiaigua Sec. Litig.*, 944 F. Supp. at 1209; *see also Backman v. Polaroid Corp.*, 910 F.2d 10, 16 (1st Cir. 1990) (the requirement to be "complete and accurate" does not mean that "by revealing one fact . . . one must reveal all others that, too, would be interesting"); *In re SeaChange Int'l*, 2004 U.S. Dist. LEXIS 1687, at *26 (securities

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[8] "At risk" is a term used to describe a generic launch of a pharmaceutical product before a determination on the merits of underlying patent litigation. *Altana Pharma AG v. Teva Pharms. USA, Inc.*, No. 04-2355 (JLL), 2007 U.S. Dist. LEXIS 67285, at *13 (D.N.J. Sept. 6, 2007) (launching a generic version is "an 'at risk launch'" when the court "has not yet rendered a decision on Plaintiffs' underlying infringement claim"). The term recognizes that any such launch, regardless of what other consequences may follow, jeopardizes the 180-day period of exclusivity the first ANDA filer is entitled to under the Hatch-Waxman Act. *See* 21 U.S.C. §355(j) (first generic company to have filed and successfully obtained approval of its ANDA granted 180-day period of exclusivity as against other generic pharmaceutical companies); *Sanofi-Synthelabo*, 488 F. Supp. 2d at 322.

laws do not require company to disclose "everything that it knows" but only to keep information disclosed "from being materially misleading").[9]

B. BMS Fully and Accurately Disclosed the Antitrust Division Investigation.

The Company's disclosures regarding the Antitrust Division investigation also were prompt, accurate and appropriate. BMS disclosed the investigation the day after the Company learned of its existence. Am. Complaint ¶ 82; Reisner Decl. Ex. I. The Company provided accurate updates concerning the investigation, its status and the underlying facts as they became known to the Company. *Id.* ¶¶ 107-108; Reisner Decl. Exs. N, O, P. This disclosure fully satisfied BMS's obligations under the federal securities laws. S*ee In re Marsh & McClellan Cos. Sec. Litig.*, 501 F. Supp. 2d 452, 471 (S.D.N.Y. 2006) (disclosure of pendency of government investigation sufficient as a matter of law); *In re Boston Scientific*, 490 F. Supp. 2d at 156 (disclosure of risk of adverse outcome of pending Department of Justice investigation sufficient as a matter of law).

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[9] Plaintiffs' contention that BMS was obligated to disclose in May 2006 that the state attorneys general had provided notice that they would not approve the initial settlement agreement and that the initial agreement had been withdrawn from the FTC pending renegotiation, Am. Complaint ¶¶ 38, 75 and 78, also is incorrect as a matter of law. As noted above, there is no obligation under Item 103 to detail "the status of the litigation . . . or the probability that the tribunal will deliver a particular decision," *Wielgos*, 892 F.2d at 518, and the process of regulatory review remained ongoing. Am. Complaint ¶ 39. The information from the regulators did not render existing BMS disclosures materially misleading. As had been previously disclosed, there remained a "significant risk" of regulatory non-approval (*see*, *e.g.*, Am. Complaint ¶ 73). Indeed, disclosing this information prematurely may have misled investors into believing that the regulatory review process had ended when it had not. In any event, an update on the status of the settlement agreement and the regulatory review process was provided on June 25, 2006. Reisner Decl. Ex. H; Am. Complaint ¶ 79.

The Amended Complaint alleges that the June 25, 2006 disclosure by BMS was false and misleading because it failed to disclose that "secret and unlawful side agreements" had been entered during the May 12 and May 24 meetings in Toronto. Am. Complaint ¶ 81.[10] Even accepting these baseless allegations as true, they are not actionable because the alleged non-disclosures did not make prior statements by BMS false and misleading. *See supra* at 9-10 (citing cases). There remained a "significant risk" that regulatory approval of the settlement would not be obtained; Apotex still could launch a generic product in the absence of a settlement; and generic entry still would

[10] This allegation relies entirely on the sensational claims of Bernard Sherman, Chairman of Apotex, Am. Complaint ¶¶ 38, 42-46, who BMS believes fabricated this account in order to sabotage the regulatory process and advance his personal financial interests. By triggering regulatory disapproval, Sherman and Apotex were able to obtain hundreds of millions of dollars of profit from the sale of infringing generic product. Am. Complaint ¶ 106; *see* S. Saul, *Marketers of Plavix Outfoxed on a Deal*, NEW YORK TIMES, August 9, 2006 at C6 (Reisner Decl. Ex. V) (article referenced at Am. Complaint ¶ 100) (quoting Sherman as confirming that Apotex was engaging in an "all out launch" of generic Plavix and predicting that it would be the "largest and most successful launch" of a generic pharmaceutical in history). Sherman and Apotex repeatedly have engaged in deceitful conduct to pursue financial profit. *See, e.g.*, *Apotex, Inc. v. Eon Labs Mfg.*, Nos. 01 Civ. 482 (AC), 02 Civ. 1604, 2007 WL 656256, at *9-*11 (E.D.N.Y. Feb. 26, 2007) (awarding litigation expenses and finding Sherman submitted backdated declaration); *Merck & Co. Inc. v. Apotex, Inc.*, 5 C.P.R. (4th) 1, at ¶ 40 (Federal Court of Canada 2000) (Sherman and Apotex held in contempt of court); *In the Matter of Bernard C. Sherman and Shermfin Corp.*, Exchange Act Release No. 34-34378, 57 S.E.C. Docket 374, 1994 WL 377139, Order and Findings (July 14, 1994) (Sherman violated anti-fraud provisions of the securities laws by concealing beneficial ownership of shares); *United States v. Medicine Club Int'l, Inc.*, No. AW-94-0373, (D. Md. August 13, 1994) (criminal plea agreement in which Apotex admitted to participating in sale of unapproved drugs to U.S. consumers). Although BMS has acknowledged that there were oral representations made by a former senior executive (Dr. Bodnar) that should have been disclosed to the FTC, BMS does not believe that there was any undisclosed "side agreement" with Apotex. Reisner Decl. Ex. P (BMS release dated June 11, 2007); Am. Complaint ¶ 108.

have serious adverse financial consequences. *See* Reisner Decl. Ex. E. The alleged "side agreements" did not render these or any other BMS statements false or misleading.

In addition, courts repeatedly have held that the "federal securities laws do not require a company to accuse itself of wrongdoing." *In re Citigroup, Inc. Sec. Litig.*, 330 F. Supp. 2d 367, 377 (S.D.N.Y. 2004) (no obligation to disclose that defendant's revenues derived from "unsustainable and illegitimate sources"). *See also United States v. Matthews*, 787 F.2d 38, 49 (2d Cir. 1986) ("so long as uncharged criminal conduct is not required to be disclosed by any rule lawfully promulgated by the SEC, nondisclosure of such conduct" is not actionable under the securities laws); *In re Marsh & McClellan Cos. Sec. Litig.*, 501 F. Supp. 2d at 471 ("a general duty to disclose corporate mismanagement or uncharged criminal conduct has been rejected").[11] Although the conduct alleged by plaintiffs may raise other legal issues, for which BMS has taken responsibility, it does not support a violation of the securities laws. BMS satisfied its obligations by accurately disclosing the Antitrust Division investigation. *In re Boston Scientific*, 490 F. Supp. 2d at 156.

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[11] *See also In re Am. Express Co. S'holder Litig.*, 840 F. Supp. 260, 269 (S.D.N.Y. 1993) (company not required to "accuse itself of antisocial or illegal policies") (quotations omitted); *In re Donna Karan Int'l Inc. Sec. Litig.*, No. 97-CV-2011 (CBA), 1998 U.S. Dist. LEXIS 22435, at *27 n.9 (E.D.N.Y. Aug. 14, 1998) (". . . securities laws do not require corporate management to direct conclusory accusations at itself or to characterize its behavior in a pejorative manner.") (quotation omitted); *Ciresi v. Citicorp*, 782 F. Supp. 819, 823 (S.D.N.Y. 1991) (". . . the law does not impose a duty to disclose uncharged, unadjudicated wrongdoing or mismanagement").

II. PLAINTIFF CANNOT ESTABLISH LOSS CAUSATION AS A MATTER OF LAW.

The Amended Complaint fails to plead and cannot plead loss causation as a matter of law because the alleged stock price declines upon which it is based plainly were linked to risks that were fully disclosed.

"A private plaintiff who claims securities fraud must prove that the defendant's fraud caused an economic loss." *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 338 (2005). This burden includes establishing "loss causation," or a "causal connection between the material misrepresentation and the loss." *Id.* at 342; *Leykin v. AT&T Corp.*, 423 F. Supp. 2d 229, 238 (S.D.N.Y. 2006) (plaintiff must establish that "the subject of the fraudulent statement or omission was the cause of the actual loss suffered") (quotation omitted). Where as here, the economic harm is linked to risks that have been accurately disclosed, there can be no loss causation as a matter of law. *See Lentell v. Merrill Lynch & Co., Inc.*, 396 F.3d 161, 173 (2d Cir. 2005) (loss must be "caused by the materialization of the concealed risk"); *In re Boston Scientific*, 490 F. Supp. 2d at 154 ("loss resulting from the materialization of a disclosed risk does not support a claim of securities fraud").

The Amended Complaint is based on stock-price declines occurring on three days: July 27, 2006 (announcement of Antitrust Division investigation of Plavix settlement); July 31, 2006 (first trading day after announcement of regulatory disapproval of Plavix settlement); and August 8, 2006 (announcement of Apotex generic launch). Am. Complaint ¶¶ 111(a), 111(b), 111(c). It is plain that these declines were linked to the risk of regulatory disapproval and the risk of a generic launch, both of which were clearly and repeatedly disclosed by BMS. Because the alleged losses resulted from the

occurrence of disclosed risks, plaintiffs cannot establish loss causation and their claims must be dismissed.

The July 27 announcement of the Antitrust Division investigation, which took place almost immediately after the Company learned of the investigation, Am. Complaint ¶ 82, Reisner Decl. Ex. I, also cannot be the basis for any claimed loss because it did not discuss the subject matter of the non-disclosures alleged in the Amended Complaint and therefore cannot have corrected any prior, allegedly misleading disclosure. *In re Merrill Lynch Tyco Research Sec. Litig.*, No. 03-CV-4080 (MP), 2004 U.S. Dist. LEXIS 2247, at *8 (S.D.N.Y. Feb. 18, 2004) (because the putative corrective disclosure "did not discuss the subject matter of the alleged fraud, as a matter of law, the decline in . . . trading price on that date cannot be considered a reaction to the disclosure of the alleged 'fraud'"). Put simply, a stock price decline following the announcement of a regulatory investigation or other "bad news" does not establish loss causation. *In re Tellium, Inc. Sec. Litig.*, No. 02-CV-5878 (FLW), 2005 U.S. Dist. LEXIS 26332, at *14 (D.N.J. Aug. 26, 2005) ("*Dura* itself makes clear that loss causation is not pled upon allegations of drops in stock price following an announcement of bad news that does not disclose the fraud"); *In re Avista Corp. Sec. Litig.*, 415 F. Supp. 2d 1214, 1221 (E.D. Wa. 2005) ("the announcement by a regulatory agency that it intends to investigate is insufficient, on its own, to plead loss causation"). Although disclosure of the criminal investigation may have suggested that regulatory approval of the settlement would not be forthcoming, the "significant risk" that regulatory clearance would not be obtained already had been fully disclosed.

Plaintiffs' allegation that the August 8, 2006 stock price decline resulted from disclosure of the damages and remedy provisions of the proposed settlement agreements

(as opposed to the Apotex generic launch announced that day), Am. Complaint ¶ 111(c), is unsupportable and contradicted by material incorporated in the Amended Complaint. Whether or not these provisions of the proposed settlement "increased the risk of a generic launch by Apotex," Am. Complaint ¶ 7, was irrelevant because Apotex already had launched its generic product. *Id.* ¶¶ 7, 99. As the media reports incorporated by reference in the Amended Complaint acknowledge, the August 8 stock-price decline resulted from the Apotex generic launch on that day.[12] This obvious reality is further confirmed by the increases in BMS share price following the preliminary injunction of the Apotex launch (share price up to $22.95 on September 1, 2006, first trading day after post-closing announcement); affirmance of the preliminary injunction (share price up to $25.35 after December 8, 2006 announcement) and entry of a permanent injunction after trial (share price up to $31.58 following June 19, 2007 announcement). Reisner Decl. Ex. R.

Moreover, had material information relating to BMS compliance "with [its] obligation to present" information accurately to the FTC, Am. Complaint ¶ 110, actually

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[12] *See, e.g.*, G. E. Jordan, *Generic Plavix Hits the Market*, NEWARK STAR LEDGER, August 9, 2006 at 59 (Reisner Decl. Ex. T) ("a Canadian drugmaker yesterday announced it began selling copycat versions of the blood-thinner Plavix, sending shares of Bristol-Myers Squibb into a tailspin"); T. Agovino and W. Witkowski, *Drug Fight Escalates; Bristol-Myers Shares Slip After Rival Launches Generic Version of Blood Thinner*, THE HOUSTON CHRONICLE, August 9, 2006 at Business, 3 (Reisner Decl. Ex. U) ("Bristol-Myers Squibb Co. shares plunged nearly 7 percent Tuesday . . . now that a generic version of its best-selling medicine has been launched by Apotex Corp."); S. Saul, *Marketers of Plavix Outfoxed on a Deal*, NEW YORK TIMES, August 9, 2006 at C6 (Reisner Decl. Ex. V) ("The generic drug maker Apotex yesterday began shipping a cheaper form of Plavix . . . . Shares of Bristol-Myers. . .were down 6.85 percent yesterday on the prospect of a major erosion of those sales").

been withheld from the market, the May 10, 2007 disclosure announcing the plea agreement with the Antitrust Division should have caused a decline in the share price of BMS stock. *See, e.g., In re eSpeed Inc. Sec. Litig.*, 457 F. Supp. 2d 266, 297 (S.D.N.Y. 2006) (corrective disclosure occurs where "market understood . . . what it did not before"). Instead, on May 11, 2007, the first trading day after the post-closing release of this news, BMS's stock price rose from $29.88 to $30.24. Reisner Decl. Ex. R. The frivolousness of the Amended Complaint is further apparent from this undeniable fact: when the alleged omissions concerning statements made during the Plavix negotiations and the criminal disposition were publicly announced in the May 10 through June 11, 2007 period, *see* Reisner Decl. Exs. N, O, & P, the price per share of BMS stock actually traded higher (range of $29.17 to $30.48) than during the March 22 through August 8, 2006 class period in which the share price allegedly was "artificially inflated" (range of $21.21 to $25.99). *See* Am. Complaint ¶ 109 (alleging "artificially inflated" stock price), Reisner Decl. Ex. R (stock price information); *Dura Pharms. Inc.*, 544 U.S. at 347 (no loss causation where plaintiff failed to demonstrate that company's "share price fell significantly after the truth became known").

III. THE SCIENTER ALLEGATIONS IN THE AMENDED COMPLAINT ARE INSUFFICIENT UNDER THE *TELLABS* STANDARD.

Dismissal of the Amended Complaint also is required because it fails to establish the "strong inference" of scienter required under the heightened pleading requirements of the Private Securities Litigation Reform Act of 1995 ("PSLRA"). *Tellabs Inc. v. Makor Issues & Rights, Ltd.*, 127 S. Ct. 2499, 2509 (2007). As the Supreme Court recently emphasized, "the inference of scienter must be more than merely 'reasonable' or

'permissible' – it must be cogent and compelling, thus strong in light of other explanations." *Id.* at 2510.

It is therefore necessary to consider "plausible opposing inferences" and whether the inference of scienter is "persuasive, effective and cogent" in light of those other possible, non-culpable inferences. *Id*. at 2509-10. "A complaint will survive . . . only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.* at 2510; *see ATSI Commc'ns Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 104 (2d Cir. 2007) (no "strong inference of scienter" where there was a "'plausible nonculpable explanation[]' for the defendants' actions"). The Amended Complaint fails to meet this exacting standard.

First, because there was no duty to disclose more detailed information concerning the terms of the Plavix settlement (or, at most, any such duty was unclear), intentional misconduct or recklessness cannot be inferred. As the Court of Appeals has observed, where a "plaintiff's claim lies in non-disclosure" and the "case does not present facts indicating a clear duty to disclose, plaintiff's scienter allegations do not provide *strong* evidence of conscious misbehavior or recklessness." *Kalnit v. Eichler*, 264 F.3d 131, 144 (2d Cir. 2001) (emphasis in original). In such cases, the more "compelling" inference, *Tellabs*, 127 S. Ct. at 2510, is that the Company believed in good faith that disclosure of the allegedly omitted information was not required. That is particularly true where, as here, there already was substantial disclosure on a subject. *See In re Geopharma, Inc. Sec. Litig.*, 411 F. Supp. 2d 434, 446-48 (S.D.N.Y. 2006) ("Given what defendants *did* disclose," there was no "obvious duty to disclose" any further information and the alleged omission therefore "cannot constitute reckless behavior" or establish a strong inference of

scienter); *White v. H&R Block, Inc.*, No. 02 Civ. 8965 (MBM), 2004 WL 1698628, at * 9 (S.D.N.Y. July 28, 2004) ("[d]efendants' failure to discuss [pending litigation] at length – and defendants did discuss it publicly in some detail . . . can hardly be characterized as 'an extreme departure from the standards of ordinary care'"); *L.L. Capital Partners, L.P. v. Rockefeller Ctr. Props., Inc.*, 921 F. Supp. 1174, 1183 (S.D.N.Y. 1996) (when duty to disclose is "debatable," allegation of scienter based on failure to disclose insufficient).

Second, in addition to a good-faith belief that no further disclosure was legally required, another obvious "nonculpable explanation," *ATSI*, 493 F.3d at 104, for not publicly reporting more detailed information about the Plavix settlement terms was so that competitors and potential competitors including other generic companies adverse to BMS in related litigation involving the Plavix patent, *see* Reisner Decl. Exs. X, Y (docket sheets from related patent litigation), could not use the information to disadvantage BMS. The Court properly may take judicial notice of these non-culpable and far more "compelling" inferences. *Tellabs*, 127 S. Ct. at 1510; *see also San Leandro Emergency Medical Group Profit Sharing Plan v. Philip Morris Cos. Inc.*, 75 F.3d 801, 809 (2d Cir. 1996) (no duty to disclose contingent marketing plans and acknowledging concern "about interpreting the securities laws to force companies to give their competitors advance notice of sensitive pricing information").

Finally, the most plausible reason BMS did not disclose the purported "secret oral side agreements" allegedly entered during the May 12 and May 24 meetings, Am. Complaint ¶ 39, is that the individuals responsible for disclosure decisions were not aware of any such agreements. As noted above, BMS believed and continues to believe there were no undisclosed side agreements with Apotex. *See* Reisner Decl. Ex. P

(June 11, 2007 BMS release); *supra* at 14, n.9. The Amended Complaint acknowledges that Dr. Bodnar was the only Company representative present at the May 12 and 24 meetings. Am. Complaint ¶ 57. The only source for the allegation that Mr. Dolan or any other BMS employee was aware of any purported "side agreements" is the inadmissible hearsay statement of Sherman, Am. Complaint ¶ 57, whose obviously self-interested assertions are entirely unreliable. *See supra* at 15; *ATSI,* 493 F.3d at 103 (dismissing complaint where plaintiff relied "at best, on speculative inferences"); *San Leandro,* 75 F.3d at 813 (dismissing complaint and rejecting attempt to "base claims of fraud on speculation and conclusory allegations") (citation omitted). The far more plausible and compelling inference is that Mr. Dolan and others at BMS did not believe there were any undisclosed side agreements with Apotex. Accordingly, the applicable heightened scienter requirement cannot be met.

The scienter allegations in the Amended Complaint fail for additional reasons. Mr. Dolan's termination as CEO, Am. Complaint ¶ 124, is not "cogent" or "compelling" evidence of scienter. *See, e.g. Malin v. XL Capital Ltd.*, 499 F. Supp. 2d 117, 162 (D. Conn. 2007) (termination not indicative of scienter because "[i]n the absence of facts connecting [defendants] to alleged fraud, it is more likely that they were terminated and resigned as a result of company mismanagement, not securities fraud"). Similarly inadequate are the allegations that company executives were motivated "to protect the exclusivity of their Plavix product, literally at all costs" or to "maintain . . . executive and directorial positions at Bristol-Myers." Am. Complaint ¶¶ 126, 141. These generalized allegations of motive are possessed by all corporate managers and are insufficient as a matter of law to establish the required *strong* inference of scienter. *See Shields v.*

Citytrust Bancorp., 25 F.3d 1124, 1130 (2d Cir. 1994) ("a plaintiff must do more than merely charge that executives aim to prolong the benefits of the positions they hold"); *Acito v. Imcera Group, Inc.*, 47 F.3d 47, 54 (2d Cir. 1995) (maintaining stock price cannot be the basis for a scienter claim or "virtually every company in the United States that experiences a downturn in stock price could be forced to defend securities fraud actions").

CONCLUSION

For the foregoing reasons, the Amended Complaint should be dismissed.

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Respectfully submitted,

DEBEVOISE & PLIMPTON LLP

By: /s/ Lorin L. Reisner

Lorin L. Reisner
Michael R. Potenza
Jacob W. Stahl
919 Third Avenue
New York, New York 10022
(212) 909-6000

Attorneys for Defendant Bristol-Myers Squibb Company